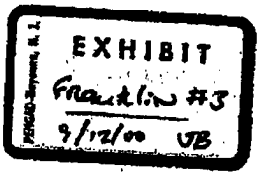
# EXHIBIT C

# DISCLOSURE OF INFORMATION BY RELATOR DAVID P. FRANKLIN PURSUANT TO 31 U.S.C. § 3730 b(2)



DISCLOSURE OF INFORMATION BY
RELATOR DAVID P. FRANKLIN
PURSUANT TO 31 U.S.C. § 3730 b(2)

## I SUMMARY OF DISCLOSURE

This disclosure details the relator's personal knowledge of a widespread pattern of illegal activity by the Parke-Davis division of Warner Lambert in the marketing and promotion of several of its prescription drug products. This illegal pattern of activity has resulted, directly and indirectly, in financial harm to the United States Government in the form of fraudulent inducement of payments for prescription drugs through the Medicare and Medicaid programs as well as direct purchases by the Veterans Administration. As a result of Parke-Davis' illegal conduct and fraud, the United States has, in some cases, paid for drug that it never intended to pay for, and in other cases, overpaid for prescription drugs. The estimated damage to the United States is presently occurring at a rate of $30 to 40 million per year.

Parke-Davis' illegal conduct has consisted of deliberate avoidance of the provisions of the Food and Drug Act as well as the regulations of the U.S. Food and Drug Administration ("FDA") applying to the promotion of "off-label" uses of its prescription drug products. Parke-Davis has also been guilty of conventional fraud in the sale of its prescription drug products, by making claims of safety and effectiveness for off-label uses where no evidence exists of safety and effectiveness. Parke-Davis has sanctioned, encouraged and organized an illegal, informal non-FDA approved program of human experimentation, financed to a substantial degree, unbeknownst to the federal government, through Medicare, Medicaid and Veterans Administration payments. This use of fraud, illegality, and avoidance of federal regulation in the promotion of its products is a deliberate, nationwide program in which Parke-Davis has invested millions of dollars over the past two years and which has substantially increased the sales of its drugs.

Parke-Davis' illegal activity has consisted of, among other things, the direct solicitation of physicians to prescribe its prescription drugs for off-label uses, the payment of illegal kick-backs to physicians who prescribe Parke-Davis products to patients who are on Medicare and Medicaid, the illegal use of "medical liaisons" in direct sales functions, the encouragement and financing of human experimentation without permission from the FDA and without proper protocols, the avoidance of federal price controls, the avoidance of state formulary restrictions, and the use of direct fraud in the sales of their products. Parke-Davis has also trained its employees in methods of avoiding detection by the FDA, and established a policy of creating false documents,

destroying documents, and using other methods of active concealment.

## II PROFESSIONAL BACKGROUND OF RELATOR, DAVID P. FRANKLIN AND HIRING BY WARNER-LAMBERT

David P. Franklin completed a bachelor of science degree in microbiology in 1987 at the University of Rhode Island. He was awarded a Ph.D. in biological science in November of 1992. He is one of several authors of a pending patent application based on research done for his dissertation[1].

In December of 1992, Dr. Franklin accepted a two year research fellowship with Harvard Medical School and the Dana-Farber Cancer Institute in Boston, Massachusetts. While at Dana-Farber, Dr. Franklin conducted basic scientific research and investigated the mechanisms of signal transduction within T-cells, co-authored five

[1] U.S. Pat. Appln. Ser. No. 08/601, 790 *Salmonella Typhimurium* Vaccine

scientific publications[2] and received various awards[3]. His fellowship was extended for a third year.

On February 20, 1996, Dr. Franklin contacted Warner-Lambert in writing about the possibility of joining the company in a field position. On March 6, 1996, Dr. Franklin was contacted by Zona Hodge, Director of Human Resources for the Northeast Customer Business Unit (NECBU) of Parke-Davis, a division of Warner-Lambert. Ms. Hodge arranged a meeting on Saturday, March 9, 1996, at the Boston Ritz Carlton Hotel where Dr. Franklin was interviewed by Phil Magistro, Associate Medical Director in Parke-Davis' Medical and Scientific Affairs, and three current medical liaisons. On Wednesday, March 13, 1996, Dr. Franklin was flown to Warner-Lambert's headquarters in Newark, NJ for a day of interviews with Hodge, Magistro, William Sigmund, M.D., Vice-President of Medical and Scientific Affairs and Michael Valentino, Vice-President of the NECBU. There, Dr. Franklin was offered the position of medical liaison which he accepted on March 15, 1996. On Friday, March 15, 1996, Dr. Franklin attended a meeting of NECBU medical liaisons in

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[2] Hutchcroft J.E., Franklin, D.P., Tsai, B., Harrison-Findik, D., Varticovski, L. & Bierer, B.E. 1995. Phorbol Ester Treatment Inhibits Phosphatidylinositol-3-kinase Activation by, and Association with CD28, a T-Lymphocyte Surface Receptor. Proceedings of the National Academy of Sciences, USA. 90:8808-8812.

Krivan, H.C., Franklin, D.P., Wang, W., Laux, D.C. & Cohen, P.S. 1992. Phosphatidylserine Found in Intestinal Mucus Serves as a Sole Source of Carbon and Nitrogen for *Salmonella* and *Escherichia coli*. Infection and Immunity, 60:3943-3946.

Franklin, D.P., Laux, D.C., Williams, T.J., Falk, M.C. & Cohen, P.S. 1991. Growth of *Salmonella typhimurium* SL5319 and Escherichia coli F-18 in Mouse Cecal Mucus: Role of Peptides & Iron. FEMS Microbiol. Ecol. 74:229-240.

Cohen, P.S., McCormick, B.A., Franklin, D.P., Burghoff, R.L. & Laux, D.C. 1990. The Role of Large Intestine Mucus in Colonization of the Mouse Large Intestine by *Escherichia coli* and *Salmonella typhimurium*. Molecular Pathogenesis of Gastrointestinal Infections. Edited by T. Wadstrom, Plenum Press, New York.

McCormick, B.A., Franklin, D.P., Laus, D.C. & Cohen, P.S. 1989. Type 1 Pili Are Not Necessary for Colonization of the Streptomycin Treated Mouse by Type 1 Piliated *Escherichia coli* F-18 and *Escherichia coli* K12. Infection & Immunity. 57:3022-3029.

[3]David S. Abraham Oncology Fellowship, 1994; National Research Service Award, Public Health Service, NIAID, 1993; Phi Kappa Phi, Elected 1989, and the President's Award for Academic Excellence, 1987.

Parsippany, NJ, and formally started as an employee on April 1, 1996.

Over the next four to six weeks, Dr. Franklin became increasingly concerned as to the illegal activities that he was witnessing and being asked to conduct. On or about the third week of May, 1996, Dr. Franklin began to record work-related telephone conversations from the Parke-Davis ASPEN voice mail system. A transcript of those recordings is attached hereto as Exhibit A. He also began to copy and retain documents. On July 10, 1996, Dr. Franklin spent the day with Phil Magistro, and John Krukar, Director of Marketing for the NECBU. As a result of these conversations and their implications, Dr. Franklin decided to leave Parke-Davis. Concerned about his involvement in illegal activities and their possible impact on his career, Dr. Franklin contacted Greene & Hoffman, P.C. for advice as to how to proceed. Dr. Franklin gave notice to end his employment effective immediately on July 29, 1996, but his resignation has not been accepted or processed and he remains on "paid administrative leave." Dr. Franklin continues to receive mailings from Parke-Davis to this day.

In the following disclosure, many conversations witnessed by Dr. Franklin, but not recorded, are recounted. These conversations, while presented as dialogue, represent Dr. Franklin's best recollection of the words spoken by those involved.

## III SUMMARY OF PARKE DAVIS' OVERALL PLAN OF ILLEGAL MARKETING

In 1994, Parke-Davis obtained FDA approval to market Neurontin (gabapentin) for use as adjuvant therapy for seizures, in dosages up to 1800 mg/d. This use represented a relatively narrow market, since it was limited to people suffering from seizures which were not adequately controlled with conventional seizure control medications. Parke-Davis' sales department recognized a significant profit potential in the off-label promotion of Neurontin for other diseases and at higher dosages (Exhibit A, Page 1-22, through 1-25; also Page 1-79 through 1-80). The decision was made to completely avoid the normal regulatory process of the FDA pertaining to the marketing of a new use of a drug and to proceed in an illegal fashion. The decision was also made to actively conceal the illegal means which would be used to market the drug. The principal component of the scheme was the hiring and deployment in the field of approximately 60 "medical liaisons", whose real function was to actively solicit physicians to promote off-label uses of Neurontin, using cash payments as a reward and incentive.

The following is a summary of the major aspects of Parke-Davis' illegal scheme (each point is later presented in greater detail in subsequent sections of this disclosure):

III (a) Parke-Davis knew that the scheme was illegal

Parke-Davis' scheme was deliberate company policy, formulated at a high corporate level, and was not the result of rogue or aberrant regional employees.

Parke-Davis' training program for its medical liaisons focused heavily on the enforcement and oversight functions of the FDA, and the means of avoiding them. The medical liaisons were told how to avoid creating written records, and the possible undesirable consequences of creating them. The issue of FDA regulations, and how to avoid them, was a regular item of discussion in the sales department. Also, false records were generated, and records were destroyed. A certain Parke-Davis employee referred to the scheme as "brazenly criminal".

III (b) Sales promotion role of the medical liaison

In the pharmaceutical industry, medical liaisons are individuals with scientific training who are available at physicians's request to provide balanced scientific information about a company's products. They have no role as sales people.

At Parke-Davis, many of the "medical liaisons" were hired directly out of the sales department. They were all trained in sales techniques, and compensated, in part, on the basis of sales. They had no discernable scientific or medical functions. They had no communication or interaction with Parke-Davis' actual medical research divisions. The medical liaisons were assigned to act as teams with the regular sales representatives. They were given lists of doctors for "cold calls", based on the size of the doctors' practices and their ability to prescribe Neurontin. They were provided with a package of monetary incentives to offer to physicians who get involved in the Parke-Davis program.

III (c) Use of kick-backs

Parke-Davis created a complex array of monetary incentives for physicians who write prescriptions for Neurontin. None of these have anything to do with scientific or medical research. These incentives include cash payments to "consultants" and "preceptors", cash payments for a "speakers bureau" and for participation in teleconferences, the award of money for scientifically irrelevant "studies", miscellaneous cash payments for access to records of patients who are taking Neurontin, travel and Olympics tickets, and other benefits. The recipients of these awards and benefits were selected by the sales department based on their ability to prescribe Neurontin and to influence other doctors to do so.

A large percentage of Neurontin patients are on Medicare or Medicaid or are veterans. Thus, the anti-kickback provisions of federal law are applicable in many of these situations.

III (d) Use of false information to persuade physicians to prescribe off-label

The medical liaisons were trained to use knowingly false information to persuade physicians to use Neurontin for off-label uses. Parke-Davis' official sales line was that since Neurontin is safe at very high doses and produced no significant side effects, there is no problem using it for off-label indications. Medical liaisons were trained to tell doctors that evidence exists that Neurontin, in high doses, is effective for control of bi-polar mental disorder, monotherapy for seizures, for control of a variety of pain states, for attention deficit disorder, for migraine, for drug and alcohol withdrawal seizures, for restless leg syndrome, and for several other diseases. There is absolutely no competent scientific evidence that Neurontin is safe and effective for any of these conditions. The only "evidence" that existed was gossip, case reports from physicians paid by Parke-Davis, self-referential studies, and rumor. The medical liaisons were also trained to misrepresent their own credentials to the physicians in order to elevate their own credibility, by saying they were "involved in research". In fact, they were purely involved in sales.

III (e) Experimentation

Parke-Davis medical liaisons, using a combination of misrepresentations and cash incentives, encouraged many physicians to experiment with their own patients by prescribing very high levels of Neurontin for a variety of off-label indications. Parke-Davis did this with the combined motives of increasing sales, generating a body of "medical practice", and generating case reports which could later be used for further off-label promotion with other physicians. Parke-Davis' sales employees expressed callous disregard for the possibility of adverse reactions occurring during these informal, non-FDA sanctioned, illegal experiments.

III (f) Destruction of records and creation of false records

Parke-Davis had an official company policy of not writing anything down, in order to minimize evidence which might be discovered by the FDA. Medical liaisons were trained in this policy. A voice mail system was established to facilitate communications without using paper. Certain incriminating documents were shredded. Other documents were falsified in order to cover up the illegality of the scheme, particularly, forms which indicated that a physician had "requested" a visit from a medical liaison, when in fact the visit was a cold-call.

Each of the above topics is hereinafter discussed in greater detail, as follows.

## IV DETAILED DISCLOSURE OF RELATOR'S KNOWLEDGE

### IV (a) Parke-Davis' knowledge that it's activities are illegal

Knowledge of the illegality of Parke-Davis' marketing activities permeated the company. This knowledge was made apparent to Dr. Franklin by company counsel, personnel from the corporate offices, his superiors and his fellow medical liaisons.

Dr. Franklin's first indication that there was illegality in Parke-Davis' marketing was, in retrospect, during his interviews. While being interviewed by Michael Valentino, questions were asked about Dr. Franklin's willingness to "work in a gray area" and "bend the rules." Later the same day, Ms. Hodge and Mr. Magistro asked about instances in which Dr. Franklin had been asked to "bend the rules" and how he had handled the conflict.

Knowledge of the company's illegal plans extended to his fellow medical liaisons. On Sunday, April 14, 1996, Dr. Franklin flew to Ann Arbor, Michigan for formal medical liaison training. That night he dined with the NECBU medical liaisons and Adrian Bal, Associate Medical Director for the West CBU. Dr. Bal, a retired general, specialized in sales to the Veteran's Administration, military, and managed care. When introduced, he referred to the Northeast medical liaisons as a "bunch of brazen criminals." He went on to describe how the liaisons' techniques were much too blunt and thinly disguised to evade discovery by the FDA. Dr. Bal then described that he'd "quit before the company would make his liaisons sell."

On Tuesday, April 16, 1996, the entire liaison group with the exception of some that had already been trained, were video-taped attending a seminar conducted by the Parke-Davis Advertising Review Committee, including Jim Parker, a former FDA official and Alan Rubinstein, a lawyer for Parke-Davis. Parker started by laying out the FDA rules and requirements and what was expected of the medical liaisons. Rubinstein then pointed out that if the liaisons broke these rules the company would not be able to offer any assistance. Both pointed out that the company was currently under the constraints of a consent decree and that a violation would result in criminal charges against the president of Warner-Lambert. One of them stated that "if you get caught violating the FDA rules, you're on your own and acting without the company's knowledge or permission." Parker and Rubinstein told the medical liaisons that:

- You must have a Physician Information Request Form ("IRF") for each call.
- You must provide a fair and balanced presentation.
- You can't close or sell.

- You can't promote a drug off label.
- You can't promote a drug pre-approval.
- You must keep accurate records of your activities.
- You can't solicit an inquiry.

At that point the video camera was turned off, and several jokes were made about it genuinely being off. Then, the liaisons were told how they should actually operate. First they were told, "More than the FDA, look out for other company representatives, they'll turn you in in a minute. We expect you to do your job out there and stay focused on sales, don't worry about this stuff, just use common sense." Then, they were told:

- If you're cold-calling with a sales representative, have him fill out the IRF form so you are covered.
- You're not out there to help the other guys and the doctors know it, so don't worry about being balanced.
- Look, without sales there is no Parke-Davis, we all have to sell on some level.
- You can talk about anything that will help the doctor to treat his patients.
- Be careful for this, but everyone wants to know about Atorvastatin, just don't leave anything behind.
- Above all, don't put anything in writing.
- It's hard to define "solicit." If you're in his face long enough he's going to ask some kind of question, and there you go.

In June of 1996, Dr. Franklin was told to attend sales training in New Jersey by two of his peer medical liaisons, Darryl Moy and Ken Lawlor. In response to Dr. Franklin's anger that such requests were coming from his peers, Moy stated that "Management isn't supposed to be scheduling you for a thing like this. Your attendance is completely unofficial so nobody wants their name associated with it." He later stated, "What management wants to do is try to figure out how to integrate medical liaisons and how to use them in the sales training program, but it has to be handled delicately." Dr. Franklin personally felt very uncomfortable with the idea of attending a sales training session. He complained to Phil Magistro who responded, but only after Dr. Franklin left for the training.

The sales training showed Dr. Franklin much about the active, national approach to off-label marketing of Neurontin and Accupril (quinapril hydrochloride). During one meeting, Jim Lamatina, Vice-President of Training, said, "We need to take a close look at the medical liaisons. I know some people see you as valuable but some people think you are going to destroy this company. For now, you are supported in the majority but I think that might change." Rich Thetchi, a Sales Trainer, stated that "the medical liaison thing is catching on throughout the country. Too bad we can't include training on how to use liaisons here, you know, the legal stuff."

At Parke-Davis, Dr. Franklin witnessed and participated in numerous conversations with many different Parke-Davis employees in which knowledge of the ongoing infractions of FDA regulations was openly discussed. This was a regular topic of discussion, as demonstrated in the voice mail tapes (Exhibit A, Page 1-8, 1-12 to 1-13, 1-24, 1-34, 1-41, 1-140 to 1-144)

One particular medical liaison, Lisa Kellett, a former Parke-Davis sales representative, expressed concerns about her personal legal exposure after being ordered to engage in illegal marketing activities in Pittsburgh, PA. Ms. Kellett feared that this high visibility activity would result in complaints to the FDA and jeopardize her career. She registered her complaints with Phil Magistro and reported the conversation to Dr. Franklin (Exhibit A, Pages 1-140 to 1-144). Mr. Magistro, in a later conversation with Dr. Franklin, dismissed her complaints and referred to her as "a little excitable." Magistro also cautioned his medical liaisons not to focus the physician's attention on the FDA regulations due to the ease with which such infractions could be reported (Exhibit A, Page 1-43 through 1-46).

In another indication of Warner-Lambert's recognition of the illegal activities they had undertaken, since his resignation, Dr. Franklin has been besieged by phone calls. He has received calls from Warner-Lambert's in-house counsel Mr. Long and it's general counsel Gregory L. Johnson requesting that Dr. Franklin meet with attorneys from the Wall Street firm of Davis, Polk & Wardwell. In addition, in spite of his resignation and cessation of work, he continues to be paid his regular salary.

IV (b) Role of medical liaisons

Parke-Davis used medical liaisons exclusively in an aggressive sales role to push off-label uses of its products. The company's official policy is best exemplified by the statement of Phil Magistro, Dr. Franklin's immediate supervisor,

> "Medical liaisons, this is Phil. I am calling in regard to the -- you know, there's a Neurontin push that's supposed to be on. What we'd like you to do is, any time you're called out, just make sure that your main focus out of what you are doing is on Neurontin. I'm not saying don't do Accupril

calls, but the idea is you're supposed to be pushing on Neurontin. I think some people have lost that message and I think a lot -- may be somewhat ineffectual in that regard. So, what we need to do is focus on Neurontin. When we get out there, we want to kick some ass on Neurontin, we want to sell Neurontin on pain. All right? And monotherapy and everything that we can talk about, that's what we want to do. Cuz, I'm embarrassed. I don't know if you guys are embarrassed. But I'm embarrassed about where we are with Neurontin. We've got to take it into our own hands and really kick some ass on it, All right? Let's do it up. Talk to you soon, bye." (Exhibit A, Page 1-2)

Another example comes from John Ford, who works at company headquarters in Morris Plains, NJ. During a meeting Dr. Franklin attended of the NECBU in Farmington, CT on April 22, 1996, Ford said,

"I want you out there every day selling Neurontin. Look, this isn't just me, it's come down from Morris Plains that Neurontin is more profitable than Accupril so we need to focus on Neurontin... We all know Neurontin's not growing for adjunctive therapy, besides that's not where the money is. Pain management, now that's money. Monotherapy, that's money. We don't want to share these patients with everybody, we want them on Neurontin only. We want their whole drug budget, not a quarter, not half, the whole thing... We can't wait for them to ask, we need get out there and tell them up front. Dinner programs, CME programs, consultantships all work great but don't forget the one-on-one. That's where we need to be, holding their hand and whispering in their ear, Neurontin for pain, Neurontin for monotherapy, Neurontin for bipolar, Neurontin for everything...I don't want to see a single patient coming off Neurontin before they've been up to at least 4800mg/day. I don't want to hear that safety crap either, have you tried Neurontin, every one of you should take one just to see there is nothing, it's a great drug."

In the pharmaceutical industry, individuals with scientific training, and in many cases, advanced graduate degrees, are intended to be the facilitators of the exchange of fair and balanced scientific information. This concept of "fair and balanced" is at the core of the medical liaison function. The ultimate goal of the medical liaison-physician interaction is to increase the quality of patient care. No one, including medical liaisons, are allowed to commercially promote off-label uses of prescription medications.

Dr. Franklin accepted the position of medical liaison with Parke-Davis believing that the position being offered met all of the requirements set forth above. He was interested in the position for the opportunities he saw to increase the quality of medicine through information exchange and to be instrumental in the

scientific development of new drugs through his involvement in clinical trials.

Dr. Franklin first heard evidence that the Parke-Davis view on the use of the medical liaison deviated from the industry norm even during the interview process. During the first interview on March 9, 1996, Phil Magistro, an Associate Medical Director, and the person who became Dr. Franklin's immediate superior, described the position as having all of the characteristics required by the FDA. However, much of the discussion concerned Dr. Franklin's ability to aggressively interact with the medical community and "get a crowd excited" with his platform skills. The others at the interview, medical liaisons Lisa Kellett, Michael Davies, Ph.D. and Joseph McFarland, discussed their work and their presence in Boston for a "consultants' meeting". This discussion focused on the medical liaison's need to, as Lisa Kellett said, "twist some arms" to motivate the physician "consultants" to accept the company's point of view on it's drug. Dr. Davies stated that "they want to know, they just don't know they want to know" which made the job easier because the physicians were usually appreciative of the information.

While discussing the career backgrounds of the medical liaisons, Dr. Franklin learned that all but one of the current medical liaisons in the northeast had previously been sales representatives, some promoted from within Parke-Davis. The newest hires, of which he would be one, were to have advanced science degrees because as Dr. Davies said, "the degree opens doors", as evident by Dr. Davies' extraordinary success in just one month on the job.

Zona Hodge called Dr. Franklin on March 11, 1996 to arrange a day of interviews at the company headquarters. During this conversation, Ms. Hodge told Dr. Franklin that "there is some question about whether your personal style is aggressive enough. Make sure you sell yourself, remember this is a sales position, you've got to be aggressive."

Dr. Franklin never received any formal scientific training on the background or benefits of Parke-Davis drugs. He did however receive a great deal of formalized training on selling techniques and strategies for evading federal regulations and competitor inquiries. In addition to the promotional materials concerning Parke-Davis products, Dr. Franklin was given copies of SellingPower Magazine, a magazine geared towards sales personnel of all fields.

In a training session in March of 1996, the medical liaisons were joined by Tom Gorga, Director of Finance for the NECBU, Mike Valentino, John Krukar, and Brion Brandes, the Financial Analyst for the CBU. This management team took the group to lunch and then reconvened the meeting to "tell us some exciting news." Gorga and

Valentino described an incentive program that provided the medical liaisons as well as the sales representatives with an all expenses paid cruise to the Bahamas should the market share of Accupril and Neurontin meet certain levels by June. There were other incentive programs, as is indicated by Exhibit B.

John Krukar then took over the presentation and described how medical liaisons were crucial to meeting this goal. "The only way we will make it [to the Bahamas] is if you as a group take ownership of the task and get out there and aggressively move share. You have to be aggressive... don't take no for an answer, if the rep doesn't close, you close, if the rep is seeing the wrong docs you see the right ones. If a high decile practice isn't using Neurontin, get in there, do your thing, then ask why. Tell them that if their patients aren't on Accupril, they're doing them a disservice. Tell the endothelial dysfunction story, reversal of CAD, everything, I don't care but you're wasting your time and our money if you don't ask for the new script when you're through. We expect a high return on investment from you guys, you're an expensive group but we know you can do it." Later in the conversation it came up that the CBU reduced its sales force in order to allow the hiring of the planned fourteen medical liaisons because it was expected that the liaisons would increase overall sales. Dr. Franklin questioned Lisa Kellett and Phil Magistro about this exchange, in particular the sales orientation for medical liaisons, but his concerns were dismissed with "John Krukar is an asshole, don't worry about it... but don't turn your back on him."

On April 1, 1996, Dr. Franklin met with his Boston co-workers at the Needham Sheraton. The field training schedule was laid out. Dr. Franklin would read up on the relevant background material and follow Lisa Kellett and Michael Davies on calls to various influential and high decile physicians. A high-decile physician is one who has a large number of patients in his practice. The Boston based medical liaisons also split up the area into territories to focus the company's "pre-launch awareness heightening effort" for Atorvastatin and Troglitazone[4]. Dr. Franklin was assigned the Lahey Clinic, UMass Medical Center, and Boston City Hospital. As an introduction to his duties, Lisa Kellett brought him to visit Dr. Stuart Chipkin of Boston City Hospital. This visit was in response to a request from the sales representative who wanted to "get Dr. Chipkin involved." Ms. Kellett was to show Dr. Franklin how to get into an office, gather information on other potential physicians, and to raise interest in the drug to "have them clamoring for it when it's launched" or to "decrease ramp up time at launch." As Ms. Kellett had previously been Dr. Chipkin's sales representative for Parke-Davis products, she maintained that role

[4] At this time, these two drugs had not been approved by the FDA for any use.

and introduced Dr. Franklin, in fact, adding that he was a physician.

Dr. Franklin was then given a list of physicians referred to as "thought leaders" or "key influencers" (Exhibit C, see also Exhibit D) because "if you convince them and get them talking, you get much more bang for your buck". These "thought leaders" were to be physicians who would be the biggest prescribers of the two, yet to be approved drugs. He was to visit these physicians to determine how receptive they would be to working with the company to build excitement and interest in the drugs by talking about the drugs. Some physicians Dr. Franklin contacted, such as Dr. David Nathan at Massachusetts General Hospital, flatly refused to work in support of a drug company or to take part in pre-approval marketing. Dr. Franklin was instructed to repeat this method until successful with each thought leader in his area. He was also provided with a packet of materials to use to convince these physicians to use Troglitazone. It consisted of medical literature discussing the problems competitor's drugs caused some patients, descriptions of clinical trials still underway for which the final results had not yet been published, programs from continuing medical education programs at which clinical researchers from Parke-Davis spoke and touted the results seen so far from these trials. Use of any of this literature is clearly trying to promote and market the use of a drug before its approval by the FDA, a clear breach of FDA regulations.

As for community or non-academic physicians and pharmacists, Dr. Franklin was instructed to cold-call physicians with or without sales representatives. Precision marketing reports were prepared by the Parke-Davis management team, and provided to Dr. Franklin, that listed the names and addresses of physicians in the area along with their prescribing information. He was provided with lists of neurologists and given the amount of Neurontin they were prescribing (Exhibit E). He was also provided with lists of physicians in fields for which the only use of Neurontin could be off-label. For example psychiatrists were being pushed for off-label treatment of bipolar disease, pediatricians were being pushed for off-label treatment of ADD and other non-neurology specialists who were being asked to prescribe Neurontin off-label for the treatment of pain (Exhibit F). The medical liaisons were to call on high decile, or large practice physicians only. When working with a sales representative, the medical liaison was brought in and introduced as an expert scientist (in what ever specialty the physician was) from Parke-Davis. Dr. Franklin was brought out specifically to talk to physicians about exciting new developments with either Neurontin or Accupril.

Parke-Davis employees told Dr. Franklin that the following procedure should be followed when presenting "The Neurontin Cold-Call Story" to a neurologist, general practitioner, or psychiatrist:

- Mention that you are the eyes and ears of Parke-Davis research and that you are gathering clinical info,
- then ask general questions about the nature of the practice.
- Mention Neurontin and its approved uses, but dismiss them as old news.
- Then ask leading questions about the number of pain patients that the practice sees.
- Then ask a series of questions that determine the practice profile for all of the potential off-label uses.
- Next reveal that Parke-Davis "has a great deal of information about the fantastic response rate of patients on Neurontin in all of these disease states."
- Move into a discussion of the clinical trials that this information is demanding,
- and the "90-95% response rate that we are seeing in more then 80% of patients."
- Present the doctor with any publications that are available and point out that many common drugs for pain treatment are in few if any publications.
- Ask the physician to place some patients on Neurontin and tell them that the medical liaison will stay in touch to help develop any case reports.
- Mention that case reports can be lucrative and can lead to clinical trials.
- Offer to do a presentation and luncheon for the entire practice or a group of his friends that will detail all of the "data" we have.
- Invite the physician to consultant meetings in the future and point out that they pay $250 plus a nice trip or meal in the city.
- If a sales representative is present they should close the sale by asking that the next patient he sees should be put on Neurontin.

When pushing Accupril (an angiotensin converting enzyme (ACE) inhibitor that has been approved for the control of hypertension as well as a treatment for heart failure), Phil Magistro described the following procedure to be followed:

- Be introduced as a cardiovascular expert from Parke-Davis research.
- Prior to meeting the doctor, determine his level of sophistication. This information would be gleaned from other sales representatives or medical liaisons at Parke-Davis.
- If the doctor was naive, present the vascular biology story and the role of tissue ACE in coronary artery disease and arteriosclerosis. Emphasize that not all ACE inhibitors are the same.

- If the doctor was well versed, jump right into the "great result we are hearing about the two clinical trials QUIET and TREND."
- Say that the TREND results are showing a 20% increase in vasodilatation upon acetylcholine challenge in patients taking Accupril.
- Say that the QUIET trial is showing a 15-25% decrease in cardiac events in people taking Accupril.
- Point out that "other ACE inhibitors have tried and failed. Accupril is the only ACE inhibitor that can reverse the course of coronary artery disease."
- Ask if the doctor uses Accupril. If not, point out that his patients will live longer and actually get better if he switches them to Accupril.
- Lead into the new drugs, especially Atorvastatin and Parke-Davis' approach to disease management.
- Offer consultantship and its benefits.
- Offer to make a formal presentation and let him know you will check back in with new developments.
- Close the sale if a sales representative isn't present.

On May 13, 1996, in a luncheon meeting with sales representative Tom Kelley, neurologist Dr. Gold in Revere, MA[5], gave Dr. Franklin a recent medical article (Exhibit G) that indicated that Neurontin use in some children with attention deficit disorder caused serious adverse effects, particularly the worsening of symptom and behavior outbursts. While driving to a dinner meeting on May 30, 1996, with Phil Magistro and Lisa Kellett, Dr. Franklin asked whether Magistro had seen the article and how he was handling physician questions about it. Magistro replied, "Yea, but its such a small number of kids, and they can just take them off if it happens, there's no permanent effect. So don't even mention it." Ms. Kellett added, "If they ask, just tell them there is a single report but there are problems with it and the kids involved had multiple problems." Dr. Franklin then asked, "But what if it's true and these kids start to get worse or hurt themselves in an outburst?" Magistro replied, "What are the chances, besides the doctor shouldn't have been using the stuff off-label anyway, [laughter], no, don't worry it will never get back to us."

At a May 30, 1996 dinner meeting at Eccola in Parsipanny, NJ, Dr. Franklin joined a conversation between Phil Magistro and Mike Valentino already in progress concerning sales Territory Managers' ("TM") introductions of medical liaisons to physicians and the need for training to better mask the actual reason for the visit.

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[5]Note that Dr. Gold had not requested any information, or requested a Medical Liaison. Kelley had called Dr. Gold's office to schedule the meeting because he had heard that the practice was growing.

Valentino: "We need to train the TM to make it look like we brought in this expert just for them, boy it makes them feel great and we look good. In that situation they will believe anything."

Magistro: "We've got to get that message across. A lot of TMs are still saying 'He can talk about things I can't', if they keep on saying that we're going to get bagged."

Valentino: "Don't worry about that, [turns to Dr. Franklin] I hope you guys aren't listening to Bill Sigmund, he's a nut. He's screwing up big time. The whole company is watching us, already they're expanding into the south and central CBU's. This program works! No one can argue with that."

Magistro: "Yea, Bill and the west are going to find themselves in the cold real soon."

Valentino: "You can't stop us now, I've got support from everyone in the Parke-Davis Marketing Team and even Tony Wild. You guys are going to be real heroes."

Later in the conversation, Valentino added "Look, if the TM's can't hack it, we'll shake them out. In the mean time you guys take the ball and get out there and drive the business. We hired you because you're the brightest, don't carry dead weight, go out and do it yourself, you don't need TM's, we've already shown that you open more doors than they can anyway."

Other meetings Dr. Franklin attended during July further defined the role of the Parke-Davis' medical liaison. During a meeting with Clinical Research an organizational chart showed medical liaisons as a sales function and thus not allowed to interface with "bona fide clinical scientists" in the field. During a period when Dr. Sigmund and Beth Attias-Yon (an Associate Medical Director in the South CBU) were discussing the medical liaison's role in clinical trials, Dr. Franklin asked fellow medical liaisons McFarland and Davies how much time they spent each month working with clinical trials. McFarland answered "Ha...less than one hour in four months" and Davies answered, "I don't know why they are doing this, we don't do it at all. The medical directors do that stuff, I think they want to make it look good."

To further enhance his sales skills, Dr. Franklin was directed to attend sales training in Morris Plains, NJ for several days during three weeks in June along with 24 new sales representatives. Dr. Franklin and another new medical liaison, Dr. Joseph Dymkowski, were "unofficial" participants in a program designed by Derek Lee, then Director of Sales Training, later marketing manager for the NECBU, to provide them with the sales techniques needed to sell products to physicians.

Proper medical liaisons, in addition to not being sales persons, are required to present fair and balanced information about their drugs. However, at Parke-Davis, Dr. Franklin was instructed that "good" results should be highly touted but that "bad" results should be hidden from view. At the same time, Dr. Franklin was given publications that used positive results, in similar small numbers of patients, to tout the off-label uses of drugs.

The role of the medical liaison at Parke-Davis is best summed up by a statement heard by Dr. Franklin at a luncheon meeting on May 31, 1996 with John Ford, John Krukar, and Ravish Gandhi, an Area Business Manager from the Pittsburgh region. Dr. Franklin heard Ford, Krukar, and Gandhi explaining that the Pittsburgh area had no medical liaison presence and as such was to be used as a model to evaluate return on investment for medical liaison. Ford explained:

> "We are going to blast the area with you guys, we need four or five of you to spend the whole week in Pittsburgh. We'll coordinate it so you will ride with TM's all day, making ten or twenty calls on high decile doctors, then do dinner programs at night. We'll set up drop off points so you can ride with every TM and get maximum utilization of your time. We'll cold-call every important doctor in the area and get the message out. The dinner programs, one for each of you every night, will drive the message home. This concentrated push in this underserved area will give us a great measure of the impact you guys have on the bottom line, you know NMOT's [New Months of Therapy]. If it works the way I think it will we'll expand the program even more."

This program was enacted during the week of July 15 to July 19, 1996, during which time four medical liaisons cold-called more than seventy physicians in the Pittsburgh area. The four medical liaisons chosen were chosen for their experienced sales backgrounds.

IV (c) Kickbacks paid to physicians

Parke-Davis has devised a number of methods of placing cash and other benefits into the hands of physicians who prescribed Neurontin, as a reward and encouragement for writing prescriptions. None of these programs is intended to produce, and none of them produces, any scientific information whatsoever. They are all exclusively sales related programs, administered exclusively by the sales department.

The most widespread program involves "consultants". The term "consultant", as used at Parke-Davis, connotes a cash payment of $250 or more to a doctor. It is reasonable to estimate that Parke-Davis has thousands of "consultants". An example of materials used

to recruit "consultants", is provided in Exhibit H. Note, in the "Faculty List" of Page 2 of Exhibit H, Phil Magistro is listed as having a Ph.D. He does not have a Ph.D.

The consultant payments are generally made through third party payers, and the payments are financed entirely by, and the recipients selected exclusively by, the sales department of Parke-Davis. On one occasion, Dr. Franklin and other medical liaison were requested to suggest consultant candidates on the basis of their ability to increase sales (Exhibit A, Pages 1-124 - 1-125). The sales representatives select the physicians who will become "consultants", and consultant payments are generally regarded as rewards or incentives to physicians to write prescriptions. The consultants' "duties" sometimes involve attending meetings. Dr. Franklin was present at three of these meetings. Nothing of scientific significance took place at those three meetings. No information was sought from or obtained from the "consultants", whose entire activity at the meetings consisted of eating, drinking, and being exposed to a Parke-Davis sales department promotion of off-label uses of Neurontin and other Parke-Davis products. In fact, the "consultant" program is intended entirely to promote sales and has nothing whatsoever to do with the exchange of scientific or medical information (Exhibit A, Pages 1-124 - 125). Dennis Burke of Parke-Davis said that the purpose of consultant-type conferences is "to really go after that business" (referring to the off-label uses of Neurontin).

A smaller program, more valuable to physicians, is the "preceptor" program. A physician selected as a "preceptor" receives a payment of $350 or more each time he is visited at his office by a Parke-Davis sales representative. The preceptor's duty is to allow Parke-Davis sales representative into his office, to discuss his patients, and sometimes actually introduce patients to the sales rep. An example of a medical liaison describing his visit to a "preceptor" is in the voice mail tapes, Exhibit A at Page 1-155 through 1-159. In this extraordinary conference, Parke-Davis employee Steve Bitman boasts that during a meeting with a preceptor, he was able to meet with two of the doctor's patients and persuade the doctor to use Neurontin experimentally and off-label on each of them. This grossly illegal behaviour was placed in the ASPEN system as an example of good work by a Parke-Davis medical liaison in getting more business for the company. Preceptors are selected and recruited by the sales department (See Exhibit I). They were even selected for drugs that were not approved for any use (see Exhibit J).

Preceptors have no scientific function whatsoever. No data is collected from them. They are not required to do research. A preceptor was always a physician who was prescribing substantial amounts of Parke-Davis products. Dr. Franklin has detailed knowledge of the preceptor program because he was briefed on the program and assigned the task of recruiting Dr. Stuart Chipkin, of

Boston, as a preceptor. He estimates that there are 75 to 100 preceptors in the northeast CBU.

Another form of giving money to physicians is the "speakers bureau" (See Exhibit D). A consultant who is a large prescriber, or a "mover and shaker", is eligible for the speakers bureau. A physician in the speakers bureau would be paid $2500 or more to deliver a talk on Parke-Davis products. Again, this money is paid through a third party but funded out of the Parke-Davis sales budget.

Similar to the speakers bureau are "teleconference consultants". These physicians are paid to make themselves available for scheduled teleconferences, which are then publicized via the sales department. Other physicians would also be paid to listen in on or participate in the teleconferences. The teleconferences had titled subjects, and generally involved off-label uses of Parke-Davis products. None of this activity had any scientific value or purpose whatsoever. It was entirely promotional in nature.

A recent special program of physician benefits was a give-away of Olympics tickets. The northeast CBU was given a budget of 10 sets of Olympics tickets for physicians and their families. The sales department made the decision as to whom the tickets should be offered. Dr. Franklin witnessed a heated argument between Lisa Kellet, Richard Grady, Darryl Moy, and Ken Lawlor about who should get the tickets. The argument was based on the comparative ability of different physicians to increase sales of Parke-Davis products. The giving away of Olympics tickets was not related to any scientific purpose.

The sales department also has a budget for direct miscellaneous payments to physicians for access to their medical records and for preparation of case reports. These payments have ranged from $50 per patient record, plus office expenses and overhead. Dr. Franklin was aware of a doctor in Florida who was paid this way for approximately 300 patient records. He knew that this was a potential benefit which could be offered to physicians whom he encouraged to write more prescriptions. This program has no scientific value whatsoever to Parke-Davis. It does not produce scientific data, or data that can be used with the FDA.

Finally, Parke-Davis has paid significant sums of money to physicians to conduct "trials" (see Exhibit O). These trials have little scientific value, because of their small size, and no value at all with the FDA. Dr. Franklin was told that one of the financial benefits he could use to tempt a doctor was the possibility that he/she could be selected for a "protocol", or paid clinical trial. However, Dr. Franklin did not have the authority to commit funds for this purpose, and he was told by Phil Magistro

that he could suggest the possibility but not make promises because the budget was already used up in this area.

Nevertheless, Dr. Franklin knows that many if not all of these small trials represent little more than a transfer of funds to physicians who write large amounts of prescriptions or who are "movers and shakers".

IV (d) Use of false information by Parke-Davis

IV (d) 1 Off-label claims

It was during the March Parsipanny training that Dr. Franklin first witnessed the scope of the off-label claims that Parke-Davis intended its medical liaisons to market. Phil Magistro presented the group with new company slides that detailed the "method" to use to increase the use of Neurontin in several different off-label practice types (See Exhibit K). The slide show contained a slide that showed the "Anecdotal Uses of Neurontin." The list included the following:[6]

- Reflex sympathetic dystrophy (RSD)
- Peripheral neuropathy
- Diabetic neuropathy
- Trigeminal neuralgia
- Post-Herpetic neuralgia
- Essential tremor
- Restless leg syndrome (RLS)
- Attention deficit disorder (ADD)
- Periodic limb movement disorder
- Migraine
- Bipolar disorder
- Amyotrophic lateral sclerosis (ALS) [Lou Gehrig's Disease]
- Drug or alcohol withdrawal seizures.

Phil Magistro explained that "this list was very important to the company but that it makes Neurontin look like snake oil, so preempt the laughter by telling your physicians that 'I'm embarrassed to show you the next slide because it makes Neurontin look like snake oil, but the fact is, we are seeing extra-ordinary results, in some cases up to 90% response in all of these conditions", that will get their attention." He went on to say that "Notice all the studies we talk about, nothing gets a doc more interested in a drug than a study." Richard Grady, a medical liaison, asked if "we have any money to place studies with our big docs." Phil Magistro instructed them to "use the potential of a

[6]This slide was often updated with the addition of a new disease state and a new version sent to Dr. Franklin. It was updated so often that it was originally kept in a different slide format than the rest of the slides he had been given.

study to get in the door, even get protocols, but don't waste too much time and don't say you can get them a study, we don't have much money left." He went on to say that "if anyone asks for back-up data say we are putting it together, then suggest that the doc put some of his patients on Neurontin and we will help him publish case reports that could help place a study in his practice. Everybody wins."

None of the off-label claims made in the slide have been substantiated, let alone approved by the FDA. Yet, as shown below, these claims are a cornerstone of the Parke-Davis scheme to increase sales of Neurontin.

1. Bipolar Disorder

Dr. Franklin, upon the order of the company, deliberately contrived reports and provided fabricated information to mislead physicians into believing that a body of data existed that demonstrated the effectiveness of Neurontin in the treatment of bipolar disease. Franklin was told during several different training sessions with Phil Magistro, John Krukar and other medical liaisons, to tell physicians that clinical trials were in place for treatment of bipolar disease with Neurontin and that the early results from this trials indicated a 90% response rate upon administration of 300mg of Neurontin three times a day and titrate up to 4800mg/d. It was widely acknowledged that this was not factual data, but that it would influence the physician to experiment with the drug in his or her bipolar patients.

For example, on July 16, 1996, Franklin met with Dr. Alexandra Accardi, in Quincy, MA. During this meeting Dr. Accardi was deceived into believing the following: a) Franklin was a clinical researcher, b) his research involved putting together a formal clinical trial for submission to the FDA on the use of Neurontin in bipolar disease, c) that a substantial body of data existed on the efficacious use of Neurontin in bipolar disease, d) that specific dosing data had been collected and that she should start dosing her patients at 900mg/d, e) formal clinical trials demonstrated that Neurontin was safe up to doses of 4800mg/d, f) the drug was also shown to be effective in other psychiatric disorders g) that there were no reports of any adverse effects in patients taking Neurontin, h) and that her prescribing of Neurontin would support the potential involvement of her practice in a formal clinical trail.

All of these statements were false and demonstrated a reckless disregard for the truth and for the safety of Dr. Accardi's patients. All of the medical liaisons served in a sales and marketing capacity and none had any research duties of any kind. Medical liaisons played no role in the design of clinical trials for submission to the FDA. The medical liaisons were instructed to indicate they had such a role to add credibility to their

statements and disguise the true nature of the call. No data existed at all to support the use of Neurontin in bipolar disease. Any such "data" was either rumor, or outright fictitious, and designed to convince the physician that they should begin to experiment with Neurontin. No scientifically credible data supported this claim of effectiveness. Dosing data was also fictitious and demonstrated a disregard for patient safety by greatly over dosing patients. No scientifically credible clinical trial data supported the safety and efficacy of Neurontin dosing over 1800mg/d. No scientifically credible data support the claim that Neurontin is an effective treatment for any psychological disease. All of these statements were made to increase sales on Neurontin by influencing physicians to experiment with Neurontin in their patients.

When positive experiences were reported during this medical liaison induced experimentation, those reports would be met with support from Parke-Davis in the form of further investigation and assistance to the physician in publication of results. When reports of adverse effects were called to the attention of Parke-Davis management, medical liaisons were instructed to actively hide these reports from physicians.

Physicians were offered a number of incentive programs when they increased their prescriptions of Neurontin. Medical liaisons were told to use the promise of a clinical trial as a carrot to increase and maintain high Neurontin prescribing rates. However, no funding was available for such trials, and their offer was merely a ploy.

2. Peripheral Neuropathy, Diabetic Neuropathy, and other Pain Syndromes

Dr. Franklin was trained and instructed to actively deceive physicians with contrived data, falsified "leaks" from clinical trials, scientifically flawed reports, or "success stories" that stated that Neurontin was highly effective in the treatment of a variety of pain syndromes. Medical liaisons were instructed to refer to a body of information that was being "called in" to Parke-Davis that showed a 90% response rate in the treatment of pain. No such body of evidence existed. These data were contrived by Parke-Davis managers in order to provide its sales force and medical liaisons with the ability to refer to "data" in their attempt to influence physicians to prescribe more Neurontin.

Parke Davis management trained the medical liaisons to use the "powerful" technique of fabricating a "leak" from the Post Herpetic Neuralgia clinical trial to support the use of Neurontin in pain. Liaisons were instructed to say "a friend of mine who's a clinical data coordinator told me the other day that the trial is going far better then anyone had expected" and that "the results will revolutionize pain management." These "leaks" were absolute lies

and were used to lend credibility to the otherwise inadequate information available to support Neurontin use in the treatment of pain.

Of the case reports that do exist in the literature on the use of Neurontin for pain, none hold any scientifically credible controls or would hold up to peer review. For example, see Exhibit L. In some cases the information is incomplete and the authors have an undisclosed relationship with Parke-Davis. Other "reports" that were submitted to physicians by medical liaisons were disguised as academic reports but were in fact commissioned by Parke-Davis to support off-label sales.

Dr. Franklin was instructed to use "success stories" which were generated, in some cases unwittingly and in others through compensation, by physicians who were convinced to prescribe Neurontin. These stories were then used to persuade other physicians to begin prescribing Neurontin. This "third party sell" was considered a powerful tool and a database of "Movers and Shakers" was generated to support this "name dropping" activity. For example, see Exhibit M. In most cases these success stories were unverifiable and did not take into consideration the entirety of the case being reported. Response rates were grossly exaggerated and in some cases wholly fabricated.

3. Monotherapy of Seizures

Dr. Franklin was instructed to "push" physicians into prescribing Neurontin as a monotherapy for the treatment of epilepsy. He was trained to present himself as a neurology specialist who was conducting research into the control of epilepsy and the mode of action of anti-epileptic drugs. Dr. Franklin would explain a unique mechanism of action and then tell the physician that Parke-Davis had developed a large body of data to support the use of Neurontin as a monotherapy. This was an outright lie. The medical liaisons had access to no data at all that demonstrated that Neurontin was effective as a monotherapy.

With reckless disregard for the health of the patient, physicians were advised that they should use Neurontin as a first line of therapy. No data supported this claim, thereby leaving patients, unknowingly, without good seizure control. Liaisons were trained to tell physicians that studies had shown that you could titrate patients off other anti-epileptic drugs. This sales strategy was referred to as a "backbone technique" in that it allowed physicians to use Neurontin for constant control while limiting the side effects from other drugs. Liaisons would make reference to "all of the prominent neurologists are using this technique". There is no data in existence to support the efficacy of this dosing regimen.

Medical liaisons were also instructed to tell the physician that a great deal of data existed that supported the safe use of Neurontin at levels that exceed 4800mg/d. Clinically significant safety data only exists at dosing levels of 1800mg/d. In some cases, medical liaisons referred to physicians that dosed patients up to 8000mg/d. Neurontin is renally excreted. No data exists that demonstrates that the kidneys and other vital organs are not damaged by these exceedingly high doses.

Dr. Franklin was forcefully instructed to withhold data from physicians that showed negative or adverse effects associated with Neurontin. On his own initiative, Dr. Franklin found two literature cites that report serious side effects and exacerbation of seizures in children. These cites had been withheld from use by the company. When brought to the company's attention, Dr. Franklin was instructed to withhold this information from physicians. This fraud has endangered the lives and well being of a number of patients.

Dr. Franklin was also instructed to withhold information that indicated that human physiology did not support the utilization of Neurontin doses above 3600mg/d. Although any dose above this level would have no physiologic relevance, dosing to 4800mg/d represented a significant sales increase and therefore the liaisons were told not to reveal this information.

4. Reflex Sympathetic Dystrophy (RSD)

Dr. Franklin was instructed to deceive physicians about the existence of data demonstrating the efficacy of Neurontin in the treatment of RSD. No scientifically credible data existed to support such a claim. Accordingly, leaks and other stories, either fabricated or completely unsupported by even the slightest amount of scientific rigor, were employed for the purpose of persuasion. Dr. Franklin was trained to refer to case reports and abstracts as "studies", which were disguised to convince the physician that a great deal of supporting data existed. For example, see Exhibit N. Although the references that did exist were poor, Dr. Franklin was instructed to avoid or hide these flaws.

5. Attention Deficit Disorder (ADD)

Parke-Davis provided medical liaisons with slides that stated that Neurontin was effective for the treatment of Attention Deficit Disorder. Absolutely no data exists to support this claim. Liaisons were instructed to tell physicians that a large number of physicians were reporting cases of complete control of the symptoms of ADD. These "reported" cases have never come to light and references to them were designed to deceive physicians. For example, see Exhibit O.

6. Restless Leg Syndrome (RLS)

Dr. Franklin was instructed by Parke-Davis to aggressively promote the use of Neurontin in the treatment of Restless Leg Syndrome. There is no scientifically credible data to support this claim but liaisons were instructed to refer to the "growing body of data that the company was collecting" and that would be published soon. For example, see Exhibit P. This body of data was fictitious and reference to it was used to influence prescribing decisions.

7. Trigeminal Neuralgia

No credible scientific data exists to support the use of Neurontin for the treatment of trigeminal neuralgia. Absolutely no data exists that demonstrate that Neurontin was nearly as effective as any of the currently available and inexpensive pain killers. However, medical liaisons were instructed to market the drug heavily for this use by using false and misleading statements about its effectiveness and safety.

8. Post-Herpatic Neuralgia

Liaisons were instructed to tell physicians that 75-90% of all PHN patients were successfully treated with Neurontin. Because a clinical trial had been designed to demonstrate the safety and efficacy of Neurontin in the treatment of post-herpatic neuralgia, Parke-Davis instructed its medical liaisons to us this clinical trial to "increase awareness" of Neurontin's effectiveness in the treatment of the painful disease. There was no actual clinical data in support of these claims, which were intended to convince physicians of the efficacy of the drug even prior to the release of any data about its efficacy.

9. Essential Tremor and Periodic Limb Movement Disorder

No data exists to support the claim of effectiveness of Neurontin for either of these neurological problems. Darryl Moy, a medical liaison, told a story about how he informed a neurologist about the extraordinary response rates of these two diseases with Neurontin: The neurologist stated that he didn't see much of these two problems but that he did see a fair amount of eye movement disorders. Darryl Moy responded that "we've got twice as much data to support its effectiveness with eye movement". Acknowledging the truth that there is no credible data to support these claims, Darryl followed up the story with a punch line: "two times nothing is still nothing". In both disease states, Parke-Davis medical liaisons are instructed to increase New Months of Therapy, a measure of prescriptions, regardless of the lies needed to be told.

10. Migraine

Migraine is a difficult to treat illness that causes a great deal of discomfort and emotional distress for its sufferers. In order to take advantage of physician and patient frustration with current treatment, Parke-Davis sought to encourage physician experimentation in these patients. As such Parke-Davis instructed liaisons to tell physicians that this drug was highly effective based on "leaks" from clinical trials. Further, experimentation would be rewarded by assistance in case report publishing, consultantships, and possible clinical trial placement. These incentives were intended to influence prescribing patterns and deceive patients and physicians alike.

11. Drug & alcohol withdrawal seizures

Absolutely no data exists that demonstrates effectiveness of Neurontin in the control of withdrawal seizures. However, medical liaisons were instructed to tell physicians that data existed and that Neurontin is both safe and effective for control of these seizures. This deception completely disregarded patient well being and falsely influenced physicians to administer Neurontin to patients that had the potential to, or were actively seizing.

12. Off-label Promotion of Accupril

In addition to the off-label marketing of Neurontin, Dr. Franklin was instructed to mislead and deceive physicians as to the efficacy of Accupril. The ACE inhibitor market in the United States is large but very competitive with nine approved ACE inhibitors currently being marketed. Parke-Davis' drug was one of the last entries into the market and as such, the company was experiencing difficulties in gaining a share of this market. In order to differentiate its product from the competition, Parke-Davis has implemented a two phase program, one legitimate, one based on deceit and fraud.

Parke-Davis is conducting two large scale trials, QUIET and TREND, that are designed to examine both the short and long term benefits of ACE inhibitor therapy. Medical liaisons, including Dr. Franklin were trained and required to market Accupril using fabricated results from these legitimate studies. The intention was to convince physicians, hospital administrators, and Veterans' Administration officials that Accupril, and no other ACE inhibitor, greatly lengthened the patient's life by reversing coronary artery disease or arteriosclerosis. There was no credible scientific evidence to support these claims, (TREND results were published on August 1, 1996, and only referred to short term effects), however, medical liaisons were told to tell physicians that Accupril greatly decreased the incidence of a number of cardiac associated events and increased patients' life span.

Medical liaisons were instructed to "hard sell" physicians by telling them that "...if your patient is on any other ACE inhibitor but Accupril, the studies show that these patients will have more heart attacks, require more procedures, and die much sooner than they would if they were on Accupril." There is no credible scientific data to support these claims. The VA and other federal agencies and personnel were given this fabricated information. These same individuals were deceived into believing that the information was coming from a company researcher and was based on hard data. Neither of these were true. The entire program to install Accupril on federal, state and HMO formularies, as well as private practitioners was designed to intentionally defraud the government and private citizens into paying for a drug that was not proven to be more effective than its low cost counterparts.

Dr. Franklin was offered incentives in the form of an all-expense paid cruise should he and his counterparts influence enough physicians to raise the Parke-Davis market share to above 10% by June of 1996. Through fraud, the company reached that goal. The company also influenced and paid "kick-backs" to a large number of physicians in the form of consultantships, research grants and vacations given to physicians that increased or promised to increase the numbers of Accupril prescriptions they wrote. A program was also instituted to influence physicians to start patients at a dose that could induce a dangerous hypotension. This policy was enforced by the halting of distribution of the ten milligram sample dose of Accupril in order to force physicians to start patients, particularly Medicare and Medicaid patients, at the larger 20 mg dose.

IV (d) 2 Similar claims made to Veterans' Administration

During Dr. Franklin's initial training he heard a speech by Adrian Bal, of the western CBU. He explained that direct sales to the Veterans Administration were handled by national account managers. He himself would "visit the circuit" from time to time, traveling around the country visiting all of the VA facilities on behalf of Parke-Davis. Bal said the VA was an important part of Parke-Davis' market, and that the Boston Veterans' "integrated service network" used $6.8 million of Neurontin and Accupril 1994 alone. He said that the liaisons duties included penetration of the VA market, but that the task had to be handled "delicately". He explained that the sales pitch to the VA was the same as it was with any other physician, and included use of Neurontin for pain syndromes and psychiatric syndromes (all off-label). He gave the liaisons some additional information about ranks and levels of authority within the VA. Dr. Franklin knows that the amount of off-label use of Neurontin had increased within the VA in part because he was assigned the task, shortly before leaving Parke-Davis, of calming the concerns of a VA pharmacist who had expressed

concern about all of the off-label non-formulary prescriptions for Neurontin and Accupril he had been asked to fill.

IV (e) Experimentation on humans

Parke-Davis actually has initiated formal clinical trials to investigate additional uses of Neurontin, for post-herpetic neuralgia and for control of pain from diabetic neuropathy. These trials are apparently ongoing and have not produced any published results.

Parke-Davis has also initiated a series of small trials for a wide variety of off-label uses of Neurontin. Exhibit Q is a partial list of such trials. These trials all have little scientific value, because of their small size, and are of no value to the FDA, even if based on good science, as a basis for approving expanded uses of the drug. For example, see Exhibit R. These trials are financed by Parke-Davis. The decisions concerning the placing and financing of these trials are sales decisions, made by the sales department and the CBU's, and not by the medical research department. Tom Gorga told the liaisons that these trials were paid for by the sales department. As noted elsewhere, these small trials have the dual purpose of financially rewarding physicians who prescribe large amounts of Neurontin, as well as promoting within the medical community the off-label uses of the drug. Recommendations for candidates for "trials" came from the medical liaisons with sales responsibilities, and are based on the ability of the candidate to influence other physicians to use Neurontin (See Exhibit S).

A third category of experimentation is conducted wholly without control, documentation, or scientific method or purpose. Parke-Davis has simply encouraged a large number of physicians to prescribe Neurontin for their patients in order just to see what happens. Parke-Davis officials, including, in Dr. Franklin's area, Phil Magistro, John Ford, and John Krukar, have expressed to Dr. Franklin the company philosophy that since Neurontin was safe in very high doses and did not have serious drug interactions or side effects, it was reasonable to try it for almost any neurological condition just to see what happens. Acting on direct instructions, Dr. Franklin encouraged many doctors to experiment with Neurontin on their patients, using the above reasoning. These physicians include Dr. Alexandra Accardi, of Quincy, MA, who was encouraged to use the drug for bipolar disorder, and Dr. Patrick Madden, of Boston, MA, who was encouraged to prescribe the drug for pain.

Other examples of the encouragement of experimentation by doctors who were receiving direct payments from Parke-Davis are contained in the tape transcripts (Exhibit A, Pages 1-56, 1-88 to 1-90 and 1-124). Dr. Franklin personally succeeded in causing at least 20 doctors to experiment with Neurontin, and he knows that every medical liaison had a much greater degree of success. He

told the doctors that the drug was known to be safe at high off-label dosage levels, and couldn't cause harm, and that there existed substantial evidence that it was effective for a wide variety of off-label conditions. He also told the doctors that the company was conducting, or planning to conduct trials for these uses, and would be interested in the doctors' results, and would pay for them, and might possibly grant a formal protocol to the doctor if his/her results warranted it. His job, as it was explained to him, was to encourage this type of experimentation and then be on the alert for "success stories", which would then be reduced to "case reports" and/or anecdotes and used in subsequent promotion of off-label use (this method was termed the "third-party sell", see Exhibit M). None of these informal experiments had protocols or scientific controls. In every such case, the drugs were simply sold on a normal basis, at a normal price. He does not believe that any of the affected patients were aware that they were involved in an experiment.

In a general sense, Parke-Davis has, by this method, created a large population of individuals who are taking Neurontin at very high off-label dosages for conditions not approved by the FDA. No scientific evidence has been presented to the FDA or even exists concerning the safety of the drug at these dosage levels or its efficacy for any of the promoted off-label uses. The entire program is nothing but a gigantic experiment intended to produce a body of "medical" learning without conducting any formal trials. Since a large number of the off-label Neurontin patients were elderly or disabled, much of this experimentation has been paid for by the federal government without its knowledge.

IV (f) Use of false records, forging of false records, destruction of records

At the April Ann Arbor training session, the medical liaisons were told, "There are certain things the FDA looks for, don't give them to them, most of all don't leave a paper trail. Anything you write down can be audited. So don't write anything down." A video tape was then played that portrayed a company being sued and an executive shredding files that detailed the company strategy. The actors discussed that they should have never put their plans in writing and that even the most innocent of hand written notes now looked sinister. This message was reaffirmed the next day by Sandra Pace, a Parke-Davis regulatory affairs specialist, who passed out pads that had a header that read "Ladies and gentlemen of the jury..." or "Your Honor, I plead ..."

Dr. Franklin is aware of an incident, consistent with Parke-Davis' policy of avoiding the creation of incriminating records, where a Parke-Davis executive officer shredded documents describing the percentage increases in off-label sales of Neurontin.

Parke-Davis also engaged in the practice of creating evidence. Parke-Davis used a form called an Information Request Form ("IRF") which was maintained to document a physician's request for a visit by a medical liaison. Presumably, this document was intended by Parke-Davis to show that the medical liaisons were not engaged in sales activities but instead, were responding to physicians requests for scientific information.

Under initial training for medical liaisons, they were told, after the video tape had been turned off, that if they were cold-calling with a sales representatives, have the representative fill out the IRF so that they would be covered. However, when asked if sales representatives could sign the IRFs instead of the physician, Jim Parker stated that the FDA would see that as a forgery. In a conversation on July 1, 1996 with Dr. Franklin and John Krukor, Phil Magistro said "I checked with people way over Jim Parker's head and it's okay to have the sales reps sign the IRF forms. Really, don't worry about it, nobody checks those things anyway." Dr. Franklin replied, "I can't even get the forms themselves." Both Magistro and Krukar laughed and Magistro said, "See what I mean, these things are low priority, if something happens then we'll produce [laugh] what they want, don't worry." Krukar added, "In fact, I wish you guys would stop asking about this stuff, it just makes everybody anxious. If you guys are that anal you should rethink if you should be part of this team. We're going places, you don't go anywhere filling out forms. If you want to fill out forms for a living, get a state job."

In the entire time Dr. Franklin worked for Parke-Davis, he never possessed a Physician Information Request Form. On May 13, 1996, in response to a request from Dr. Franklin for IRF's, Parke-Davis sales representative Tom Kelley gave Dr. Franklin two interoffice memos (Exhibit T) that said that two doctors had requested information. When he handed over the memos, Kelley said, "You know that they didn't request the information, but if these make you feel legal, I'll write as many as you want."